February 8, 2021

Merit Medical Systems, Inc.
Lindsay Martin
Regulatory Affairs Specialist
1600 West Merit Pkwy.
South Jordan, Utah 84095

Re: K100569
Trade/Device Name: Merit Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Lindsay Martin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 11, 2011. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.02.08 07:54:50 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Merit Medical Systems, Inc.
c/o Ms. Lindsay Martin
1600 West Merit Parkway
South Jordan, UT 84095

MAR 11 2011

Re: K100569
Trade Name: Merit Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: February 26, 2011
Received: March 1, 2011

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anna R. Vachon

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100569

Device Name: Merit Embolectomy Catheter

Indications for Use:

The Merit Embolectomy Catheter is intended for use for the removal of fresh, soft emboli and thrombi from vessels of the arterial system.

Not for use in cerebral vasculature.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100569

Section 5
510(k) Summary for K100569

MAR 1 1 2011

General Provisions

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 West Merit Parkway, South Jordan, UT 84095
Telephone Number:	(801) 208-4187
Fax Number:	(801) 253-6905
Contact Person:	Lindsay Martin
Date of Preparation:	February 26, 2010
Registration Number:	1721504

Subject Device

Trade Name:	ASAP Catheter
Common/Usual Name:	Merit ASAP Embolectomy Catheter
Classification Name:	Catheter, Embolectomy

Predicate Device

Trade Name:	Pronto V3 Extraction Catheter, Model 5003
Classification Name:	Catheter, Embolectomy
Premarket Notification:	K063371
Manufacturer:	Vascular Solutions, Inc.

Classification

Class II per 21 CFR § 870.5150

Product Code:	DXE
Review Branch:	Division of Cardiovascular Devices

Intended Use

The intended use of the Merit Embolectomy Catheter is to remove or aspirate fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral vasculature.

Device Description

The Merit Embolectomy Catheter is a dual lumen rapid exchange catheter, compatible with 0.014"/0.36 mm guide wires with related accessories. The catheter has a maximum outer diameter of 0.068"/1.73mm and a working length of 140 cm. The catheter has a radiopaque marker band located approximately 2 mm proximal to the distal tip. The catheter has three (3) non-radiopaque positioning marks located approximately 90cm, 100 cm, and 110 cm proximal of the distal tip.

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of the following documents, and were shown to meet the

acceptance criteria that were determined to be applicable to the safety and efficacy of the device:

- ISO 10555-1, *Sterile, single-use intravascular catheters, Part 1. General requirements.*
- ISO 10555-2, *Sterile, single-use intravascular catheters, Part 2. Angiographic catheters*
- ISO 594-2, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- ISO 11135, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- ISO 10993-1, *Biological Evaluation of medical Devices Part 1: Evaluation and Testing,* and the FDA Modified ISO 10993 Test Profile
- The following is a list of all significant testing that was successfully completed:

Surface Condition
Force at Break
Freedom from Leakage 1 – Leak under Pressure
Freedom from Leakage 2- Aspiration Leak
Dimensional Verification

- Outside Diameter
- Effective Length
- Usable Length
- Depth Marks
- Tip Angle

Radio-detectability
Visual
Aspiration
Flow
Lubricious Coating Effectiveness – Coating Lubricity and Durability Test and Accelerated Aging Assessment
Coating Integrity- Dye Test
Lubricious Coating Length
Guide Wire Compatibility
Stiffness- Proximal, Mid, Distal Section
Kink Test- Proximal, Mid, Distal Section
Marker Band Retention
Rapid Exchange Lumen Attachment
Simulated Use Testing:
Tortuous Path- Tracking
Tortuous Path- Guide Wire
Tortuous Path- Crossing a deployed stent
Tortuous Path- Soft emboli aspiration
Biocompatibility Tests

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility

Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions

- bubble emission
- dye penetration
- seal peel tensile strength
- burst strength
- visual inspection

Summary of Substantial Equivalence

Based on the indications for use, design, and safety and performance test results, the subject Merit Embolectomy Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Pronto V3 Embolectomy Catheter manufactured by Vascular Solutions, Inc.